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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,050	03/15/2001	Dick Stelpflug	53130/29860	7281

7590

06/04/2002

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,050

Applicant(s)

STELPFLUG, DICK

Examiner

Medina Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213..

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 1-18 are pending in this application and are under examination.

Information Disclosure Statement

Initialed and dated copy of Applicant's IDS, Paper No. 4 is attached to the instant Office action.

Drawings

No drawings have been filed with the instant application.

Objections

The specification is objected to because of the following: The statement of deposit in the specification, page 29, does not comply with the deposit requirement set forth in 37 CFR 1.801-1.809. The deposit statement in the specification must be amended to include the deposit accession number.

Claims 1, 6, and 9 are objected to for failing to recite complete Accession information. The ATCC Accession No. must be filled in as appropriate.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

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art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The statement on page 29 of the specification indicates Applicants' intention to make an enabling deposit of the claimed invention with the ATCC is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. A deposit of at least 2500 seeds is required for enablement purpose. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and that the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 C.F.R. 1.808. See 37 CFR 1.809 for additional explanation of these requirements.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

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(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

2. Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is drawn to a method for identifying inbred corn seed G3001. However, the seed has not been deposited, and the specification does not disclose a repeatable process to reproduce the claimed seed. Therefore, a person skilled in the art would not be able to practice the claimed invention without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-5, 7-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In all claims that recite "G3001", the ATCC deposit should follow, for clarification.

In claim 1, ---said--- should be inserted before "seed" for proper dependency. Dependent claims 2-5, 7-8, 10, 12-18 are included in the rejection.

Claims 1, 6, and 9, ---under---, should be inserted before "accession".

In claim 2, ---growing--- should be inserted before "seed", for clarification.

In claim 3, "regenerable cells of G3001" is unclear. It is suggested that --- of inbred line--- be inserted before the first "G3001"; and --- the inbred line--- before the second "G3001", for clarification. Also, "the" after "expressing" should be deleted. Dependent claim 4 is included in the rejection.

In claim 4, "the cells or the protoplasts of the tissue" is indefinite. It is suggested that "the" before "cells" be deleted, and ---of the tissue culture--- be inserted after "protoplasts".

In claims 5, --- inbred line--- should be inserted before "G3001", for clarification.

In claim 7, "the method comprising" should be immediately followed by a method step, e.g. "crossing".

In claim 8, ---the hybrid--- should be inserted before "seed", for proper antecedent basis.

In claim 9, ---inbred corn seed--- before "G3001", for clarification.

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In claims 12 and 15, "A" should be replaced with ---The---, for proper dependency; ", including in the plant" should be replaced with ---- comprising----, for clarification.

In claims 13 and 16, "A" should be replaced with ---The---, for proper dependency; ", including" should be replaced with ---- comprising----, for clarification.

In claim 14; it is unclear as to how the transgene arises in the hybrid seed.

In claims 15-16, is the mutant gene an endogenous gene or a transgene?

In claim 17, it is unclear what is the source of the mutant gene?

In claim 18, line 3, "the selected plant" (singular) lacks antecedence; in line 4, "using" is an indefinite method step. Also, it is unclear what is meant by "progeny of seed"?

Written Description

Claims 6- 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed invention lacks written description under current written description guidelines.

The claims are drawn to hybrid corn seeds/plants or F1 generation plants produced from crossing two inbred parent corn plants, wherein the identity of only one of the inbred parent plant is known, and the other one is unknown.

The specification does not describe all of the F1 generation plants, in terms of their morphological and physiological characteristics. While the specification disclose unique

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morphological and physiological characteristics of the inbred corn line G3001, the claims are not limited to those F1 generation plants that retain all of the morphological and physiological characteristics of the inbred corn plant G3001. Moreover, no genetic markers unique to G3001 and which are maintained in the progeny plants have been disclosed. Claims 7 and 8 are directed to hybrid seed/plant having at least one ancestor of inbred corn plant G3001. The claims encompass progeny plant/seed of multiple generations having unknown identifying characteristics, wherein G3001 might be utilized only in the first generation cross. Since identifying characteristics have not been disclosed for the F1 generation plants, the characteristics of subsequent outcrossed generations have similarly not been described. Applicants have not described the physiological and morphological characteristics common to all of the claimed hybrid corn seed/plants having at least one ancestor of inbred corn plant G3001.

Claims 14 and 17 recite transgenes and mutant gene, however, the claims don't describe the phenotypic effects of expression of said transgenes or said mutant gene. Therefore, the hybrid plants/seeds of claims 14 and 17 are not described. Therefore, given the lack of written description as discussed above, one skilled in the art would not recognize from the specification that Applicants were in possession of the invention as broadly claimed at the time the invention was made.

The Federal Circuit court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43

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USPQ2d 1398 (Fed. Cir. 1997). The court also stated that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material”. *Id.* Further, the court held that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of members of the genus”. *Id.*

In the instant case, the disclosure of a single corn inbred line, G3001, does not provide an adequate written description for the claimed genus, hybrid corn plants/seeds, wherein only one parent is known or where only one ancestor of the plant is known to be G3001, and the rest of the ancestors are unknown. Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol. 66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Buendgen (US Patent 5, 866, 763(A), filed Sept. 1996) .

Buendgen teaches an inbred corn line, designated as ZS01220, plants, plant parts, and progeny plants thereof, tissue culture methods, hybrid seeds and plants produced by crossing the inbred line ZS01220 with at least one other corn line. The inbred line ZS01220 can be used as female or male line, has good combining ability with other inbred, has good germination quality, has high inbred seed yield, and possesses good tolerance to a number of diseases (see columns 6-14). The reference teaches the inbred includes at least one mutant gene and transgenes (column 3, lines 22-35). The claimed hybrid plant/seed differs from the prior art corn/seed, in that it has one parent or at least one ancestor that is G3001 inbred corn plant. There are insufficient specific characteristics that distinguishes the claimed corn plants/seeds from the prior art corn plant/seeds. Therefore, the claimed invention is anticipated by or, in the alternative, is obvious over the prior art.

See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product- by- process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

No claim is allowed.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24

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hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

May 30, 2002
mai



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